into the process as appropriate. **RESULTS:** Two main linguistic and conceptual issues emerged during the translation process. Firstly, when an original item used more than one adjective to cover a single concept, some languages only had one term to express this. Secondly, there was the challenge of using culturally appropriate expressions for taboo concepts such as suicide and self-harm, to ensure homogenous response across all languages. **CONCLUSIONS:** The language versions of the GAD-7 and PHQ-9 were established according to a rigorous standardized methodology to facilitate international comparison and pooling of data. The linguistic validation process aims to ensure conceptual equivalence across different language versions on the basis of a pre-defined concept list explaining what the original instrument should measure. The process as a whole supports the advantage of integrating international feedback on concepts and wording during the development of questionnaires.

PMC73

EVALUATION OF GLP-1 PRODUCT ATTRIBUTES IN TREATING PEOPLE WITH TYPE-2 DIABETES IN US: COMPARING TIME-TRADEOFF AND WILLINGNESS-TO-PAY METHODOLOGIES

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OBJECTIVES: To assess patient utilities for cost utility analyses in health economics two different ways of revealing preferences have been compared. Time trade-off (TTO) and willingness-to-pay (WTP) surveys have been completed comparing patients' preference in product propositions. TTO yields estimates of the amount of time that patients would be willing forego to achieve preferred products attributes, and WTP yields estimates of the amount of money that patients are willing to pay for products attributes. Despite their widespread use, results of the two methodologies have not, to our knowledge, been compared directly in diabetes. **METHODS:** The two methods were used to evaluate the reactions of people with type-2 diabetes to two GLP-1 injectable diabetes medications that varied on four attributes: efficacy in controlling blood glucose (measured by HbA1c), dosing frequency (twice-daily vs. once-daily), incidence of hypoglycemia, and incidence of nausea. To maximize statistical power and allow comparisons across patient groups, a large internet-based survey (more than 500 respondents) was conducted in U.S. with four categories of self-identified patients who were sampled based on their medication history, and randomly assigned to either the TTO or WTP. **RESULTS:** Results suggest that the WTP methodology yields greater face validity and sensitivity than TTO (100% of respondents prefer the superior profile in WTP vs. 96% in TTO). Data from conjoint analysis designed to establish the importance of each of the four product attributes in the decision-making process used by patients reveal similar patterns of results for the two methodologies. **CONCLUSIONS:** Regardless of whether patients were in the group assigned to TTO or WTP, patients perceive efficacy (HbA1c control) to be the most important product attribute, followed by incidence of nausea. Patients evaluated the incidence of hypoglycemia and dosing schedule as less important relative to the HbA1c control and nausea in the decision-making process.

PMC74

QUALITY-ADJUSTED LIFE YEARS SAVED BY PREVENTION OF HEAD INJURY THROUGH ENFORCEMENT OF HELMET LAW

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OBJECTIVES: To evaluate the potential long-term health impact of helmet law, we calculated the loss of quality-adjusted life year (QALY) under different proportions of helmet wearing among the motorcyclists. **METHODS:** The quality-adjusted life expectancies for helmeted and non-helmeted motorcyclists were estimated by adjusting the survival function based upon the Head Injury Registry with quality of life measures assessed under the EQ-5D questionnaire. We took Hualien County, where a lower rate of helmet wearing (77%) was reported, as an example to calculate the expected numbers of prevented head-injured cases by multiplying the population at risk with the incidence rate of head injury for helmeted and non-helmeted motorcyclists. As different proportions of helmet-wearing and different proportions of full face helmet in motorcyclists were assumed, the expected numbers of prevented cases were calculated, which were multiplied with the loss of QALE of an average case to predict the potential benefit of helmet use. **RESULTS:** Under the current proportion of helmet wearing, the annual loss associated with head injured was 4346.9 QALYs in Hualien County. If the proportion of helmet wearing could be increased to 100%, the health benefit saved was estimated 1434.3 QALYs. If 80% of them used full face helmet, the total gain was increased to 2500 QALYs. **CONCLUSIONS:** The health benefit of helmet protection for head injury can be determined under units of quality-adjusted life year (QALY) and directly applied in future cost-effective analyses for public health policy.

PMC75

MEANINGFUL VERSUS USEABLE RESPONSES TO PREFERENCE SURVEYS: INSIGHTS INTO IMPROVING THE VALIDITY OF HEALTH UTILITY SCORES

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OBJECTIVES: To identify the types of and reasons for unusable preference survey responses with the goal of informing improvements in health utility assessment methodology. **METHODS:** We define typologies that represent unusable responses from health utility surveys; present evidence from the literature on the frequency of such responses; present empiric data on the rationale for such types of responses; and discuss methods for handing data that contain such responses, and implications for interpreting analytic results based on health utility data. **RESULTS:** Potentially unusable health utility survey responses include (1) illogical, (2) inconsistent, (3) invariant, and (4) "protest" responses, plus (5) refusals. These responses may represent simple mistakes or misunderstandings of the survey task, which introduce noise into results, or they may be intentional responses to the parameters of the survey task that may confound respondents' other values with the value of the health state being assessed. Unusable responses can be avoided through anticipation and careful design of survey instruments, particularly for specific populations and health states, including cognitive testing prior to fielding. Unusable responses can also be omitted from analyses or analyzed separately. **CONCLUSIONS:** Unusable health utility survey responses challenge the validity of utility estimates and all analyses that incorporate these values, so it is critical to minimize these responses. Mechanisms to correct errors are useful, but may not address true preferences that are in response to elements of the measurement task and hence will not be corrected. Correction mechanisms may include tailoring the task to particular situations when bias is anticipated, such as parent valuations of children's states or individuals who express religious beliefs. Recognition of the prevalence of unusable data in health utility data sets and identifying methods for handling these errors is essential to understand the accuracy and precision of results and analyses that depend thereon.

PMC76

AN ASSESSMENT OF THE EVIDENCE TO SUPPORT THE USE OF LINGUISTIC VALIDATION INTERVIEWS AS AN INTEGRAL PART OF THE TRANSLATION OF PROS FOR USE IN MULTI-NATIONAL TRIALS

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Linguistic validation interviews are considered a vital step in the generally accepted methodology for the translation of PRO measures. The translated PRO measure is administered to 5 or more native-speakers of the target language who also have a diagnosis of the condition of interest. **OBJECTIVES:** The objective of this study was to determine whether there is any evidence to suggest that the changes made are significant enough to make the step worthwhile. **METHODS:** Examples of linguistic validation changes were gathered from completed PRO translation projects. For one scale for which 26 translations were developed, changes made at the linguistic validation stage were examined quantitatively and qualitatively in order to determine the number of changes made and the nature of these changes. The number of changes made per language as a result of the linguistic validation step ranged from 0 to 11, with a mean of 1.4 changes. The changes made can be categorised as follows: Items where participants reported they did not understand. Items where participants reported that they understood, but probing made it clear that confusion had arisen. Items where participants picked up on vocabulary that was not what they would usually use, and items where participants spotted spelling and grammatical errors. **RESULTS:** Whilst in purely numerical terms, the contribution of linguistic validation to the translation process may seem small; in terms of the importance of those changes and in the confirmation of accuracy of the translated concept, its contribution is great. Whilst the translation may appear to be "correct" in other stages, only linguistic validation interviews show if the target population understands the translation as intended. **CONCLUSIONS:** The goal of translation of a PRO instrument is to achieve conceptual equivalence, and linguistic validation is arguably the most important step in assuring this.

PMC77

DEVELOPMENT AND VALIDATION OF AN E-PRO TEMPLATE ADMINISTERED VIA A WEB-BASED INTERFACE

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BACKGROUND: As electronic patient-reported outcome (ePRO) use expands, questions have arisen regarding the effect of presentation form and style on patient interpretation and whether there is an optimal format to ensure clarity, ease of use, and data quality. **OBJECTIVES:** To develop and validate a standardized ePRO interface of common PRO question formats for use on desktop and tablet PCs to streamline ePRO study implementation. **METHODS:** A web-based application was developed for desktop and tablet platforms with 52 demographic and clinical questions representing Likert-type, dichotomous, VAS and numeric rating scales. Adults from the general population were recruited through newspaper advertisements to participate in questionnaire completion and a cognitive debriefing interview. Participants answered questions on either desktop or tablet PC and then reviewed the alternate format during the interview. Alternative question formats were reviewed to obtain further respondent insight and recommendations. **RESULTS:** Participants: N = 47: mean age 54 years (23 to 79), 51% female; 49% reported a chronic condition. 13%<= igh school education. Average completion time: desktop (n = 22) = 11 minutes; tablet PC (n = 25) = 13 minutes, with all participants finding their completion time acceptable. A total of 53% preferred desktop to tablet. Respondents found question formats easy to answer, except items requiring date and time entry (resolved through minor instruction revisions) and the VAS. The VAS was presented three ways: anchors at 0 and 100, hashmarks every ten digits, and hashmarks only with a display of the number selected. 77% preferred hashmarks; 83% liked the number displayed. No participants changed their answer after the number appeared. **CONCLUSIONS:** Respondents provided useful information on their perception and preferences for question format presented